K112018

510(k) Summary

JAN 30 2012

510(k) Notification
Smart-Read EZTest – Steam Biological Indicator

Sponsor information
:
Mesa Laboratories, Inc.
12100 W. 6th Ave
Lakewood, CO 80228

Contact:	Wendy Royalty Sr. Director, BI Ops Quality & Regulatory Affairs 8607 Park Drive Omaha, NE 68127 Phone: (402) 593-0781 Fax: (402) 593-0921 Email: wroyalty@mesalabs.com
Prepared on:	July 11, 2011
Device:	Trade name: Smart Read EZTest – Steam Biological Indicator Common name: Self-contained Biological Indicator for Steam
Manufacturing Facility:	10 Evergreen Drive Bozeman, MT 59715 FDA facility registration #: 3026231
Classification name:	Indicator, Biological Sterilization Process (21 CFR 880.2800(a))
Classification:	Class II
Predicate Device:	ProTest Steam (K041386 & K082756) Smart-Read EZTest Steam (K093794)

DESCRIPTION

The biological indicator consists of a self-contained unit that includes bacterial spores of *Geobacillus stearothermophilus* ATCC #7953 inoculated onto a paper filter carrier and a small glass ampoule containing modified Tryptic Soy Broth with Bromocresol Purple acting as a pH indicator encased in a plastic vial that serves as the culture tube. Smart Read EZTest – Steam is intended for use in monitoring the efficacy of steam sterilization processes with minimum exposure times of 20 minutes at 121 °C gravity displacement, 10 minutes at 132°C gravity displacement and 3 minutes at 132°C flash gravity displacement cycles.

INDICATIONS FOR USE

Mesa Smart Read EZTest – Steam is a self-contained Biological Indicator intended for monitoring the efficacy of steam sterilization processes. The SCBI may be used in the following steam sterilization cycles:

Cycle Type	Cycle Temp	Cycle Exposure Time
Gravity	121°C	30 Minutes
Gravity	132°C	10 Minutes
Flash Gravity*	132°C	3 Minutes
Pre-Vac	132°C	4 Minutes
Pre-Vac	135°C	3 Minutes

*Unwrapped nonporous devices only

Mesa Smart Read EZTest has a validated reduced incubation time of 10 hours.

OPERATIONAL PRINCIPALS

The Smart Read EZTest – Steam Biological Indicator is placed with a load in the sterilization chamber and subjected to a normal steam sterilization cycle. The unit is then removed and activated by crushing the glass media ampoule inside. The processed unit and an unprocessed (control) unit are incubated at 60 +/- 2°C for 10 hours.

During incubation, the available food supply (Tryptic Soy Broth) and temperature promote growth of any viable spores. As viable spores germinate and consume the provided nutrients waste products are released, increasing the acidity of the media which lowers the pH and causes a color change from purple to yellow.

Evidence of growth by color change and/or turbidity within 10 hours should be interpreted as a failure to meet the conditions necessary for sterilization, provided signs of growth are present in the control unit.

STATEMENT OF SIMILARITY TO LEGALLY MARKETED PREDICATE DEVICE

The subject device Smart Read EZTest – Steam is identical in composition and function to the legally marketed predicate device ProTest – Steam (K041386 & K082786) and Smart Read EZTezt Steam (K093794). This submission is to expand the label claims for the device #K093794 to include 121°C gravity and 132°C gravity/flash gravity cycles.

ELEMENT	SMART READ EZTEST – STEAM (Subject Device)	PROTEST – STEAM (K041386 and K082756) (Predicate Device)	SMART READ EZTEST – STEAM (K 093794) (Predicate Device)
Intended Use: ❑ Method of sterilization ❑ Process Parameters	Steam 121°C gravity – 30 minutes 132°C gravity – 10 minutes 132°C flash gravity – 3 minutes* 132°C prevacuum – 4 minutes 134°C prevacuum – 3 minutes	Steam 121°C gravity; 121°C – 135°C prevacuum 10 minute 132°C gravity and 3 minute 132°C flash gravity	Steam 121°C – 135°C prevacuum
Organism: Spore Species & Strain	*Geobacillus stearothermophilus* ATCC#7953	*Geobacillus stearothermophilus* ATCC#7953	*Geobacillus stearothermophilus* ATCC#7953
Viable spore population	Minimum standard population 1.0×10^5	$1.0 - 4.0 \times 10^{(x)}$ standard population 10^5	Minimum standard population 1.0×10^5
Resistance characteristics: ❑ D-value ❑ Z-value ❑ Survival/Kill Window	1.5 – 3.0 minutes @ 121°C NLT 10 sec. @ 132°C NLT 8 sec. @ 134°C NLT 8 sec @ 135°C Not Less than 10°C Calculated per USP Survive time: @ 121°C NLT 5 min. @ 132°C NLT 1 min. @ 134°C NLT 40 sec. @ 135°C NLT 40 sec.	1.5 – 3.0 minutes @ 121°C NLT 10 sec. @ 132°C NLT 8 sec. @ 134°C NLT 8 sec @ 135°C Not Less than 10°C Calculated per USP Survive time: @ 121°C NLT 5 min. @ 132°C NLT 1 min. @ 134°C NLT 40 sec. @ 135°C NLT 40 sec.	1.5 – 3.0 minutes @ 121°C NLT 10 sec. @ 132°C NLT 8 sec. @ 134°C NLT 8 sec @ 135°C Not Less than 10°C Calculated per USP Survive time: @ 121°C NLT 5 min. @ 132°C NLT 1 min. @ 134°C NLT 40 sec. @ 135°C NLT 40 sec.
Culture Conditions	60°C +/- 2 °C for 10 hours	55-60°C for 24 hours	60°C +/- 2 °C for 10 hours
Storage Conditions	Room temperature	15-27°C, 30-70% RH	Room temperature
Shelf-life	24 months	18 months	24 months

*Unwrapped nonporous devices only

DESCRIPTION OF TESTING (NON-CLINICAL DATA)

Testing was performed in accordance with AAMI/ISO 11138-1:2006 and AAMI/ISO 11138-3:2006 to validate the labeled claims and performance characteristics of Smart Read EZTest – Steam.

Three separate lots of product manufactured from three different primary spore crops were tested for resistance, spore population, and effectiveness in gravity cycles. For all lots tested, the above parameters and overall effectiveness in monitoring routine steam sterilization cycles has been demonstrated.

STATEMENT OF SAFETY AND EFFECTIVENESS

Based on the similar claims, design and results from the above mentioned testing, the Smart Read EZTest – Steam Biological Indicator has been demonstrated to be substantially equivalent to and therefore, as safe and effect as, the legally marketed devices ProTest– Steam (K041386 and K082756) and Smart Read EZTest – Steam (K093794).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 30 2012

Mesa Laboratories Incorporated
C/O Ms. Wendy Royalty
Senior Director, BI Ops, Quality Assurance & Regulatory Affairs
Bozeman Manufacturing Facility (SGM Biotech)
10 Evergreen Drive
Bozeman, Montana 59715

Re: K112018
Trade/Device Name: Mesa Smart Read EZTest - Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: January 25, 2011
Received: January 26, 2011

Dear Ms. Royalty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

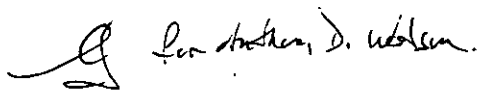
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112018

Indications for Use Statement

510(k) Number

Device Name Mesa Smart Read EZTest – Steam

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Prescription Use _____ AND/OR Over-The-Counter Use ___X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claxton-Willis
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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